

CLAIMS

1. A method of treating or inhibiting menopausal or postmenopausal disorders in a perimenopausal, menopausal, or postmenopausal woman in need thereof, which
5 comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.
2. The method according to claim 1, wherein the conjugated estrogens is
10 conjugated equine estrogens, USP.
3. The method according to claim 2, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.
- 15 4. The method according to claim 3, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.
5. The method according to claim 4, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.
- 20 6. The method according to claim 1, wherein the conjugated estrogens is synthetic conjugated estrogens, A.
7. A method of treating or inhibiting vasomotor symptoms in a perimenopausal,
25 menopausal, or postmenopausal woman in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.
- 30 8. The method according to claim 7, wherein the conjugated estrogens is conjugated equine estrogens, USP.
9. The method according to claim 8, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.
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10. The method according to claim 9, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.
11. The method according to claim 10, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.
12. The method according to claim 8, wherein the vasomotor symptom is hot flushes.
13. The method according to claim 7, wherein the conjugated estrogens is synthetic conjugated estrogens, A.
14. The method according to claim 13, wherein the vasomotor symptom is hot flushes.
15. A method of inhibiting or retarding bone demineralization or treating or inhibiting osteoporosis in a perimenopausal, menopausal, or postmenopausal woman in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.
16. The method according to claim 15, wherein the conjugated estrogens is conjugated equine estrogens, USP.
17. The method according to claim 16, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.
18. The method according to claim 17, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.
19. The method according to claim 18, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.
20. A method of treating or inhibiting vaginal or vulvar atrophy; atrophic vaginitis; vaginal dryness; pruritus; dyspareunia; dysuria; frequent urination; urinary incontinence; urinary tract infections in a perimenopausal, menopausal, or

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postmenopausal woman in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.

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21. The method according to claim 20, wherein the conjugated estrogens is conjugated equine estrogens, USP.

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22. The method according to claim 21, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.

23. The method according to claim 22, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.

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24. The method according to claim 23, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.

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27. A method of lowering cholesterol, triglycerides, Lp(a), or LDL levels; inhibiting or treating hypercholesteremia; hyperlipidemia; cardiovascular disease; atherosclerosis; peripheral vascular disease; restenosis, vasospasm; or inhibiting vascular wall damage from cellular events leading toward immune mediated vascular damage, in a perimenopausal, menopausal, or postmenopausal woman in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.

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28. The method according to claim 27, wherein the conjugated estrogens is conjugated equine estrogens, USP.

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29. The method according to claim 28, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.

30. The method according to claim 29, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.

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31. The method according to claim 30, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.

32. A method of treating or inhibiting free radical involvement in the development of cancers, central nervous system disorders, Alzheimer's disease, bone disease, aging, inflammatory disorders, peripheral vascular disease, rheumatoid arthritis, autoimmune diseases, respiratory distress, emphysema, prevention of reperfusion injury, viral hepatitis, chronic active hepatitis, tuberculosis, psoriasis, systemic lupus erythematosus, amyotrophic lateral sclerosis, aging effects, adult respiratory distress syndrome, central nervous system trauma and stroke, or injury during reperfusion procedures in a perimenopausal, menopausal, or postmenopausal woman in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.

33. The method according to claim 32, wherein the conjugated estrogens is conjugated equine estrogens, USP.

34. The method according to claim 33, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.

35. The method according to claim 34, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.

36. The method according to claim 35, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.

37. A method of treating or inhibiting dementias, neurodegenerative disorders, and Alzheimer's disease; providing neuroprotection or cognition enhancement in a perimenopausal, menopausal, or postmenopausal woman in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.

38. The method according to claim 37, wherein the conjugated estrogens is conjugated equine estrogens, USP.

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39. The method according to claim 38, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.
- 5 40. The method according to claim 39, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.
41. The method according to claim 40, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.
- 10 42. A pharmaceutical composition for use in treating menopausal or postmenopausal disorders, which comprises conjugated estrogens, a dosage of about 1.5 mg medroxyprogesterone acetate, and a pharmaceutical carrier.
- 15 43. The composition according to claim 42, wherein the conjugated estrogens is conjugated equine estrogens, USP.
44. The composition according to claim 43, wherein the dosage of conjugated equine estrogens, USP is about 0.45 mg.
- 20 45. The composition according to claim 43, wherein the dosage of conjugated equine estrogens, USP is about 0.30 mg.
46. A pharmaceutical oral dosage unit which comprises which comprises conjugated estrogens, a dosage of about 1.5 mg of medroxyprogesterone acetate, and a pharmaceutical carrier.
- 25 47. The dosage unit according to claim 46, wherein the conjugated estrogens is conjugated equine estrogens, USP.
- 30 48. The dosage unit according to claim 47, wherein the medroxyprogesterone acetate is micronized.
49. The dosage unit according to claim 47, wherein the dosage of conjugated equine estrogens, USP is about 0.45 mg.
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50. The dosage unit according to claim 47, wherein the dosage of conjugated equine estrogens, USP is about 0.30 mg.

5 51. A method of minimizing or reducing levels of breast pain in a woman receiving hormone replacement therapy, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.

10 52. The method according to claim 51, wherein the conjugated estrogens is conjugated equine estrogens, USP.

53. The method according to claim 52, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.

15 54. The method according to claim 53, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.

20 55. The method according to claim 54, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.

56. A method of minimizing spotting or breakthrough bleeding; or achieving amenorrhea in a woman receiving hormone replacement therapy, which comprises orally providing to said woman continuously and uninterruptedly over the treatment
25 period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.

57. The method according to claim 56, wherein the time for minimizing spotting or breakthrough bleeding or achieving the onset of amenorrhea is hastened.

30 58. The method according to claim 57, wherein the conjugated estrogens is conjugated equine estrogens, USP.

59. The method according to claim 58, wherein the daily dosage of conjugated
35 equine estrogens is between about 0.625 mg and about 0.3 mg.

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60. The method according to claim 59, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.

5 61. The method according to claim 60, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.

62. A method of increasing bone mineral density in a perimenopausal, menopausal, or postmenopausal woman in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a combination of conjugated estrogens and a daily dosage of about 1.5 mg of medroxyprogesterone acetate.

63. The method according to claim 62, wherein the conjugated estrogens is conjugated equine estrogens, USP.

15 64. The method according to claim 63, wherein the daily dosage of conjugated equine estrogens is between about 0.625 mg and about 0.3 mg.

20 65. The method according to claim 64, wherein the daily dosage of conjugated equine estrogens, USP is between about 0.45 mg and about 0.3 mg.

66. The method according to claim 65, wherein the daily dosage of conjugated equine estrogens, USP is about 0.3 mg.

25 67. The pharmaceutical composition according to claim 42, wherein the conjugated estrogens is synthetic conjugated estrogens, A.

68. The pharmaceutical dosage unit according to claim 46, wherein the conjugated estrogens is synthetic conjugated estrogens, A.

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